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OCT 21 2011

510(k) SUMMARY as required per 807.92(c)

Submitter:

Name, Title, and Telephone Number of Contact:

Mats Granlund, Ph.D.
Director Quality & Regulatory Affairs
St. Jude Medical Systems AB
Uppsala, Sweden
Phone: (+ 46) 0 18 161000
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email:

Date of Submission: August 3, 2011

Product Code: DRG

Classification Name: Radio Frequency Physiological Signal Transmitter and Receiver

Class: II

Establishment Registration: 8030904

Legally Marketed Device Identification: PressureWire Net

Proposed Device Description:

PressureWire Net is a radiofrequency physiological signal transmitter and receiver that is used for conditioning a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g., a host system.

PressureWire Net receives signals from the manufacturer's PressureWire and from a standard external pressure transducer, and then transmits those signals to a host system for further calculation and presentation. The subject device expands the contact range to also include a standard USB connector.

Proposed Intended Use:

PressureWire Net is intended to condition physiological signals from measuring devices (PressureWire and an external pressure transducer), transmit and receive via radiofrequency, and

reconditions the signals to its original format so that those can be displayed on and/or recorded in a receiving device (RadiAnalyzer Xpress or other Monitor systems). The physiological signals can also be distributed via cable.

Indication for Use:
PressureWire Net is indicated to condition a physiological signal from the cardiovascular system, transmit and receive via radiofrequency, and recondition the signal to its original format so that it can be displayed. The physiological signal can also be distributed via cable.

Predicate Devices:

- 510(k): K092105
  Trade Name: RadiAnalyzer Xpress
  SE Date: 01/19/2005
  Manufacturer: Radi Medical Systems AB, Inc.

- 510(k) : K080813
  Trade Name: PressureWire
  SE Date: 7/01/2008
  Manufacturer: Radi Medical Systems AB, Inc.

Substantial Equivalence:

Assessment of non clinical performance data for equivalence:
The PressureWire Net was tested in accordance with applicable standards and internal design control procedures and was determined to be as safe and effective for its intended use as the predicate device(s).

Assessment of clinical performance data for equivalence:
Clinical performance evaluation based on literature review and product performance of the device compared to the predicate device indicates that the PressureWire Net is substantially equivalent to the predicate devices.

Sterilization:

Not Applicable. The system is not supplied sterile.

Biocompatibility:

Not Applicable. The device does not directly contact the user or patient.

Standards and Guidance Documents for Reference:

Standards No	Standards Organization	Standard Title	Version
60601-1	IEC	Medical Electrical equipment - Part 1: General requirements for safety and essential performance	2005-12
60601-1-2	IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance –Collateral standard: Electromagnetic compatibility - Requirements and Tests	2007-03
60601-1-4	IEC	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems	2000-04
60601-2-34	IEC	Medical electrical equipment – Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment	2000-10
C22.2 No.601.1-M90	CAN/CSA	Medical Electrical Equipment - Part 1: General Requirements for Safety	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 21 2011

St. Jude Medical Systems AB
c/o Mr. Mats Granlund
Palmbladsgatan 10
Uppsala
Sweden SE-751 35

Re: K111854
Trade/Device Name: PressureWire Net (AO USB Receiver, WI-Box, WI-Box PSU kit, WI-Box Xpress cable, PW USB Receiver)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG
Dated: August 3, 2011
Received: August 8, 2011

Dear Mr. Granlund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known) K111854

Device Name PressureWire Net

Intended Use PressureWire Net is intended to condition physiological signals from measuring devices (PressureWire and an external pressure transducer), transmit and receive via radiofrequency, and reconditions the signals to its original format so that those can be displayed on and/or recorded in a receiving device (RadiAnalyzer Xpress or other Monitor systems). The physiological signals can also be distributed via cable.

Indication for Use:
PressureWire Net is indicated to condition a physiological signal from the cardiovascular system, transmit and receive via radiofrequency, and recondition the signal to its original format so that it can be displayed. The physiological signal can also be distributed via cable.

Prescription Use X AND/OR Over – The- Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(Please Do Not Write Below This Line – Continue on Another Page if Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111854